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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/938,009	08/23/2001	Clark M. Whitehead	P-188	1119

7590

05/23/2005

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EXAMINER

KIM, VICKIE Y

ART UNIT

PAPER NUMBER

1618

DATE MAILED: 05/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/938,009

Applicant(s)

WHITEHEAD ET AL.

Examiner

Vickie Kim

Art Unit

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 and 38 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-29 AND 30 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

RCE acknowledged

A request for continued examination(RCE) under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 01, 2004 has been entered.

Status of Application

Acknowledgement is made of amendment filed 3/01/2004. Upon entering the amendment, the claims 1, 7 and 38 are amended and the claims 30-37 and 39 are canceled.

The claims 1-29 and 38 are pending and presented for the examination.

Response to Arguments

1. Applicant's arguments filed 3/1/04 have been fully considered but they are not persuasive.
2. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does

Art Unit: 1618

not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Applicant's argument based on "obvious to try" rationale are improper for the instate situation. What would have been obvious to try would have been to vary all parameters or try each of numerous possible choices until one possibly arrived at a successful result, where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful.. In others, what was obvious to try was to explore a new technology or general approach that seemed to be a promising field of experimentation, where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it." *In re O'Farrell*, 853 F.2d 894, 903, 7 USPQ 2d 1673, 1681(Fed. Cir. 1988). In instant case, there are no numerous possible choices. The references teach specifically the compound employed herein is useful for treating autoimmune disorders, and one of ordinary skill in the art known that lupus erythematosus is an autoimmune disorder.

The arguments based "all autoimmune disorders are not alike" are not persuasive. Note, there are respects that " all autoimmune disorders are not alike," such as the etiologies. But there are some respects that all autoimmune disorders are alike, e.g. they all share the common symptom that cells and/or antibodies arising from and directed against the individuals own tissues. Sperl, teaches broadly the treatment of autoimmune disorders with compound 38. Although these diseases have different pathogenesis, they share the common symptoms that treatable by the same compound.

Art Unit: 1618

The skilled artisan, in possession of the teachings of Sperl, would have been motivated to employ compound 38 in treating any autoimmune diseases, including absent evidence to the contrary.

Thus, the claims are maintained as rejected in 103 rejection(substantially same as previous one issued) and the summary of 103 rejection is following.

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 1-29 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sperl et al(US 6,066,634) in view of Berkow et al(The Merch Manual of Medical Information, Home ed., 1997, p. 253, of record).

Sperl et al(US'634, hereinafter) teach compound 38, the elected specie herein, in example 1, see cols. 16-17, claims 1 and 28 in particular. US'634 also teaches that the said compounds are known PDE inhibitors and that they do not substantially inhibit COX-1 and COX_2, see col.5, lines 19-30 and col. 28, line 49-col.29, line 9. US'634 also teaches the employment of its compounds in a method of treating autoimmune diseases, see col. 5, lines 8-18.

US'634 does not particularly teach lupus erythematosus as an autoimmune disease. However, Berkow et al(Merck manual) teaches that lupus erythematosus is an autoimmune disease. It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ compound 38 in a method of treating lupus.

One of ordinary skill in the art would have been motivated to employ compound 38 in a method of treating lupus because compound 38 is known to be useful in methods of treating autoimmune diseases, a class of diseases which includes lupus.

It is noted that the newly added limitations in preamble does not have patentably weight because the compound 38 has been taught in the primary reference, therefore, it is inherently met and does not render the claims patentably distinct over the prior art of the record.

Conclusion

1. No claim is allowed.
2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 571-272-0579.

The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Chris Low be reached on 571-272-0953. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

Application/Control Number: 09/938,009

Page 6

Art Unit: 1618

you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).

VICKIE KIM
PRIMARY EXAMINER

Vickie Kim
May 16, 2005
Art unit 1618